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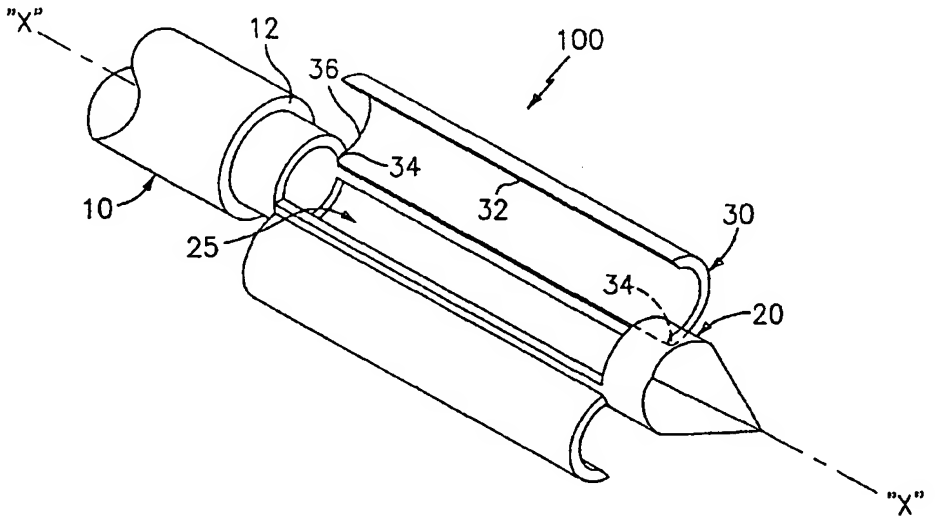
(54) Title: BIOPSY APPARATUS AND METHOD



(57) Abstract: A biopsy apparatus for taking internal sample from a patient that employs a needle with at least one cutting element that in a first position defines a portion of the outside cylindrical circumference of the needle and in a second position, the at least one cutting element is expanded beyond the circumference of the needle to form an expanded tissue cutting configuration. A method is contained wherein a biopsy apparatus is positioned at least partially within a portion of tissue to be sampled. The at least one cutting is expanded from a first folded position to a second cutting position and a vacuum is applied to augment tissue prolapse. The apparatus rotated to sever a tissue sample. The vacuum source draws the tissue sample from the tissue port through the hollow portion of the needle and the hollow outer tube. Multiple sequential samples can then be taken or the biopsy apparatus placed into the first portion and withdrawn from the patient.

WO 02/062226 A1

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BIOPSY APPARATUS AND METHOD

BACKGROUND

1. Technical Field

The present disclosure relates to instruments and methods used for obtaining tissue samples. More particularly, the present disclosure relates to minimally invasive biopsy instruments and methods for obtaining tissue samples.

2. Background of Related Art

It is often necessary to sample tissue in order to diagnose and treat patients suspected of having cancerous tumors, pre-malignant conditions and other diseases or disorders. Typically, in the case of suspected cancerous tissue, when the physician establishes by means of procedures such as palpation, x-ray or ultrasound imaging that suspicious conditions exist, a biopsy is performed to determine whether the cells are cancerous. Biopsy may be done by an open or percutaneous technique. Open biopsy removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy). Percutaneous biopsy on the other hand is usually done with a needle-like instrument and may be either a fine needle aspiration (FNA) or a core biopsy. In core biopsy, as the term suggests, a core or fragment tissue is obtained for histologic examination which may be done via frozen section or paraffin section.

The type of biopsy utilized depends in large part on the circumstances present with respect to the patient and no single procedure is ideal for all cases. Core biopsy, however, is extremely useful in a number of conditions and is being used more frequently.

Intact tissue from the organ or lesion is preferred by medical personnel in order to arrive at a definitive diagnosis regarding the patient's condition. In most cases only part of the organ or lesion need be sampled. The portions of tissue extracted must be indicative of the organ or lesion as a whole. In the past, to obtain adequate tissue from organs or lesions within the body, surgery was performed so as to reliably locate, identify and remove the tissue. With present technology, medical imaging equipment such as stereotactic x-ray, fluoroscopy, computer tomography, ultrasound, nuclear medicine and magnetic resonance

imaging, may be used. These technologies make it possible to identify small abnormalities even deep within the body. However, definitive tissue characterization still requires obtaining adequate tissue samples to characterize the histology of the organ or lesion.

The introduction of stereotactic guided percutaneous breast biopsies offered alternatives to open surgical breast biopsy. With time, these guidance systems have become more accurate and easier to use. Biopsy guns were introduced for use in conjunction with these guidance systems. Accurate placement of the biopsy guns was important to obtain useful biopsy information because only one small core could be obtained per insertion at any one location. To sample the lesion thoroughly, many separate insertions of the instrument had to be made.

Biopsy procedures may benefit from larger tissue samples being taken, for example, tissue samples as large as 10 mm across. Many of the prior art devices required multiple punctures into the breast or organ in order to obtain the necessary samples. This practice is both tedious and time consuming.

One further solution to obtain a larger tissue sample is to utilize a device capable of taking multiple tissue samples with a single insertion of an instrument. Generally, such biopsy instruments extract a sample of tissue from a tissue mass by either drawing a tissue sample into a hollow needle via an external vacuum source or by severing and containing a tissue sample within a notch formed on a stylet. Such devices generally contemplate advancing a hollow needle into a tissue mass and applying a vacuum force to draw a sample into the needle and hold the same therein while the tissue is extracted.

A continuing need exists for percutaneous biopsy apparatus and methods which can reliably extract adequate biopsy sample(s) with a single insertion of the biopsy instrument.

SUMMARY

A biopsy apparatus is provided that employs an expandable cutter with a hollow needle. The needle contains at least one cutting element that in a first position defines a portion of the outside cylindrical circumference of the needle and in a second position forms an expanded cutting element with a cutting edge that rotates along the longitudinal axis of the needle. The biopsy apparatus employs a vacuum through a central lumen draw tissue samples through the hollow needle and outer tube and is capable of multiple sequential tissue

samples. The biopsy apparatus is returned to the first position prior to withdrawal from the patient.

A biopsy method is provided wherein a biopsy apparatus, including at least one cutting element that in a first position defines a portion of the outside cylindrical circumference of the needle and in a second position forms an expanded cutting element with a cutting edge that rotates along the longitudinal axis of the needle.

The invention, together with attendant advantages, will be best understood by reference to the following detailed description of the invention when used in conjunction with the figures below.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the presently disclosed biopsy apparatus are described herein with reference to the drawings, wherein:

FIG. 1A is a frontal perspective view of one configuration of the biopsy apparatus using an expandable needle with the cutting elements folded in a first position;

FIG. 1B is a frontal perspective view of one configuration of the biopsy apparatus utilizing an expandable needle with the cutting elements expanded into an unfolded second position;

FIG. 1C is a side view of one configuration of the biopsy apparatus using an expandable needle with the cutting elements expanded into an unfolded second position;

FIG. 2A is a side view of a second configuration of the biopsy apparatus utilizing a needle with an expandable cutter with the cutting elements at least partially enclosed in an outer tube in a first position; and

FIG. 2B is a longitudinal cross sectional view of a second configuration of the biopsy apparatus utilizing an expandable cutter with the cutting elements expanded to a convex shape beyond the body of the needle.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now in specific detail to the drawings in which like referenced numerals identify similar or identical elements throughout the several views, and initially to FIG. 1A, the biopsy apparatus and method utilizing an expandable cutter 100 (hereinafter referred to as

"biopsy apparatus 100") includes an outer tube 10, a hollow needle 20, and at least one expandable element 30.

For purposes of clarity, only the details of the working of the distal ends of outer tube 10 and needle 20 are illustrated in detail. The respective proximal ends of outer tube 10 and needle 20 may be attached to a suitable handle or actuator to facilitate operation of biopsy apparatus 100 or the other embodiments and configurations disclosed herein. For example, biopsy apparatus 100 may include a housing wherein outer member 10, needle 20, and adjustable shutter like cutting mechanism 30 are housed. The housing may include suitable known driving and actuating mechanisms. In one embodiment penetrating member may be rapidly movable into position at the target tissue location by a suitable drive mechanism, such as, for example, potential energy devices, drive motors, pneumatic devices, or any other suitable drive mechanism. Outer tube 10 can be translated longitudinally along the "X" axis in both a proximal and a distal direction to expose or at least partially cover the at least one cutting elements 30 of needle 20 in a folded first position. Outer tube 10 is preferably fabricated from a medical grade plastic.

Needle 20 can be rotated about the "X" axis within outer tube 10. Needle 20 and outer tube 10 are sufficiently sealingly engaged to preclude excessive vacuum losses. Hollow needle 20 is preferably made of a medical grade metal with a piercing tip.

The at least one cutting element 30 is positioned near the distal end of needle 20. A longitudinal cutting edge 32 of the at least one cutting element 30 extends at least partially beyond the external circumference of needle 20. Cutting element 30 defines a portion of the cylindrical circumference of needle 20 in a first position. Biopsy apparatus 100 includes a vacuum source (not shown) to withdraw tissue samples. The at least one cutting element 30 is preferably made of a medical grade metal having cutting edge 32 formed along the longitudinal edge thereof.

In FIG. 1B, needle 20 is extended distally from distal end 12 along the "X" axis to expose the at least one cutting element 30. The at least one cutting element 30 is pivotally connected to needle 20 by at least one pivot point 34. A beveled proximal end is formed on the at least one cutting element 30 thereby defining cutting edge 32. From the proximal perspective, rotating biopsy apparatus 100 in a clockwise direction about the "X" axis engages the exposed cutting edge 32 of the at least one cutting element 30, forcing it to

rotatably open from the folded first position to an unfolded expanded cutting second position. Further rotation of the biopsy apparatus in the expanded position rotates cutting edge 32 through the tissue and cuts a large cylindrical sample from the tissue. Biopsy apparatus 100 includes a vacuum source of sufficient power to draw a tissue sample from tissue port 25 through hollow needle 20 and hollow outer tube 10. Cutting edge 32 is shown as a straight edge, but it can take the form of other shapes such as serrated. Similarly, biopsy apparatus 100 can be configured to engage cutting edge 32 upon counter-clockwise rotation or upon either a clockwise or counterclockwise rotation.

As shown in FIG. 1C, the at least one cutting element 30 contains a beveled proximal end 36. Distal end 12 of outer tube 10 includes a flaring of the inside circumference that forms a bevel that is configured to interface with bevel 36. The withdrawal of the distal end of needle 20 into outer tube 10 creates a cam type mechanical action on the at least one cutting element 30 thereby displacing cutting element 30 and returning cutting edge 32 into the folded position.

In operation biopsy apparatus 100 or any of the other embodiments or configurations disclosed herein may be inserted by suitable known techniques. For example, biopsy apparatus 100 may be inserted by motor driver or spring fired mechanisms. Alternatively, biopsy apparatus 100 may be inserted manually. In either arrangement, biopsy apparatus 100 or any of the other embodiments or configurations may be configured as a hand held apparatus or as part of a frame mounted device. An example of such a device is an image guided positioning apparatus such as a stereotactic imaging machine. Any suitable imaging modality may be used to guide biopsy apparatus to the target tissue.

Referring to FIGS. 1A through 1C, in the initial first position biopsy apparatus 100 is configured for piercing with the at least one cutting element 30 at least partially enclosed within outer tube 10 and the tip of needle 20 exposed. Upon proper positioning of biopsy apparatus 100 within the patient, outer tube 10 is withdrawn proximally from a first position at least partially covering the at least one cutting element 30 to a second position exposing a sufficient length of needle 20 for at least one cutting element 30 to be fully exposed. A rotation of needle 20 in a clockwise direction about longitudinal axis "X" engages the at least one edge 32 with the tissue of the patient to be sampled, rotating the at least one cutting element 30 into an expanded open position. The continued rotation of needle 20 along

longitudinal axis "X" engages cutting edge 32 of the at least one cutting element 30 with the patient's tissue. If one cutting element 30 is used, rotation of needle 20 through 360° after cutting element 30 has been deployed will result in the cutting of a tissue sample from the patient. It is envisioned that if any number of cutting elements greater than one is used, that a rotation of needle 20 through an angle equal to 360° divided by the total number of cutting elements will be sufficient to completely sever a sample of tissue from the patient. The tissue sample can then be withdrawn through the biopsy apparatus 100 by applying a vacuum to tissue port 25 through the center of outer tube 10 and hollow needle 20. Biopsy apparatus 100 can then be repositioned for a second sampling or withdrawn from the patient all together.

Referring now to FIG. 2A, an alternative embodiment of a biopsy apparatus utilizing an expandable cutter is generally shown as 200 (hereinafter referred to as "biopsy apparatus 200"). Biopsy apparatus 200 includes an outer tube 210, a needle 220, and at least one expandable element 230. Needle 220 includes a distal end 222 having a needle tip, a proximal end 224, and a shaft 226. Distal end 222 and proximal end 224 are connected by at least one cutting element 230. In addition, distal end 222 contains a longitudinal reduced diameter shaft 226 extending proximally through proximal end 224 and outer tube 210. The at least one cutting element 230 is a bendable metallic strip or wire that connects distal end 222 with proximal end 224 and forms a tissue port 225. Outer tube 210 can be translated longitudinally along the "X" axis in both a proximal and a distal direction to expose or at least partially cover the at least one cutting element 230 with a longitudinal length D1. A longitudinal edge 232 of the at least one cutting element 230 defines a portion of the cylindrical circumference of needle 220 in a first position. Biopsy apparatus 200 includes a vacuum source (not shown) to withdraw tissue samples. Needle 220 can be rotated about the "X" axis within outer tube 210. Needle 220 and outer tube 210 are sufficiently sealingly engaged to preclude excessive vacuum losses.

In FIG. 2B, when shaft 226 and distal end 222 are held in position and proximal end 224 is forced distally along longitudinal axis "X," the at least one cutting element 230 is compressed and deformed to bend from a first position that does not generally exceed the outside circumference of needle 220 to a second position that expands beyond the outside circumference of needle 220 to form a convex shape between distal end 222 and proximal end

224. In this process the longitudinal length D1 of the at least one cutting element 230 is reduced to a longitudinal length D2. While depicted as convex, the preformed shape of cutting element 230 could take a variety of geometric shapes upon compression such as triangular, square, or trapezoidal, for example, that could be advantageous in differing tissue sampling locations and conditions. The at least one cutting element 230 is configured with a cutting edge 232 along one or both edges that can also include serrations, or other similar devices to enhance the cutting of tissue samples, depending on the desired application. While needle 220 is in the second position, with the at least one cutting edge 232 in the expanded convex shape, needle 220 can be rotated through 360° about the "X" axis in order to cut a tissue sample. Biopsy apparatus 200 includes a vacuum of sufficient power that it can draw a tissue sample from tissue port 225 through hollow needle 220 and outer tube 210.

Referring now to FIGS. 2A and 2B, in the initial first position biopsy apparatus 200 is configured for piercing with at least one cutting element 230 at least partially enclosed within outer tube 210 and the tip of needle 220 exposed. Upon proper positioning within the patient, outer tube 210 is withdrawn proximally from the first position at least partially covering the at least one cutting element 230 to the second position exposing sufficient length of needle 220 for the at least one cutting element 230 to be fully exposed. The application of a distal force upon proximal end 224 while holding distal end 222 via shaft 226 in position then translates at least one cutting element 230 from a first position within the outer circumference of needle 220 to a second position expanding the at least one cutting element beyond the circumference of needle 220 into a convex shape by placing the at least one cutting element 230 in compression. Needle 220 including the at least one cutting element 230 having cutting edge 232 can then be rotated about longitudinal axis "X" to engage the surrounding tissue. The continued rotation of needle 220 about the longitudinal axis "X" through a 360° rotation cuts a tissue sample from the patient that is retained in tissue port 225. The tissue sample can then be withdrawn from tissue port 225 through the biopsy apparatus 200 by placing a vacuum through hollow outer tube 210 and needle 220. Biopsy apparatus 200 can then be repositioned for a second sampling or withdrawn from the patient. The withdrawal of biopsy apparatus 200 includes proximally extending proximal end 224 while holding shaft 226 and distal end 222 in position. This force translates at least one cutting element 230 from the expanded cutting element convex shaped second position to the first position of the at least

one cutting element 230 within the circumference of needle 220 by placing proximal end 224 under tension along the longitudinal axis "X." Once the at least one cutting element 230 is in its first position within the circumference of needle 220, needle 220 can then be withdrawn into outer tube 210 and biopsy apparatus 200 then withdrawn from the patient.

Although the illustrative embodiments of the present disclosure have been described herein with reference to the accompanying drawings, it is to be understood that the disclosure is not limited to those precise embodiments, and that various other changes and modifications may be affected therein by one skilled in the art without departing from the scope or spirit of the disclosure. All such changes and modifications are intended to be included within the scope of the disclosure.

WHAT IS CLAIMED:

1. A biopsy apparatus comprising:

an outer tube defining a longitudinal axis;

a needle translatably receivable within the outer tube and rotatable about the longitudinal about the longitudinal axis, the needle being provided with at least one radially expandable cutting element near a distal end thereof; and

a vacuum source operatively coupled to the needle to draw a severed tissue sample through the needle of the biopsy apparatus.

2. A biopsy apparatus according to claim 1, wherein the at least one cutting element is configured and adapted to have a first position wherein the at least one cutting element defines a portion of the outside cylindrical circumference of the needle and a second position wherein the at least one cutting element is expanded to a tissue cutting configuration.

3. A biopsy apparatus according to claim 2, wherein the at least one cutting element includes at least one longitudinal cutting edge.

4. A biopsy apparatus according to claim 3, wherein the at least one cutting element is an arcuate panel having a first longitudinal edge pivotably connected to the needle and wherein a second longitudinal edge is a cutting edge.

5. A biopsy apparatus according to claim 4, wherein the arcuate panel has a first position which closes a tissue port formed in the hollow needle and a second position which opens the tissue port and orients the panel for cutting.

6. A biopsy apparatus according to claim 3, wherein the needle includes a shaft portion translatably extending through the outer tube and an enlarged distal end; and wherein the at least one cutting element is a bendable strip having a proximal end integral with a distal end of the outer tube and a distal end integral with a proximal surface of the enlarged distal end.

7. A biopsy apparatus according to claim 6, wherein the bendable strip has a first position in which the bendable strip has a configuration substantially equal to the outer circumference of the enlarged distal end of the needle when the needle is in a most distal position and a second position in which the bendable strip has a radially expanded configuration when the needle is in a proximal position relative to the most distal position.

8. A method of taking internal tissue samples with a biopsy apparatus comprising the steps of:

positioning a needle in a first position containing an expandable cutting element in proximity to a portion of tissue of a patient to be sampled;

translating the needle from a first position wherein the cutting element defines a portion of the cylindrical circumference of the needle to a second position wherein the cutting element forms an expanded cutting element;

rotating the needle about a longitudinal axis to cut a tissue sample, the longitudinal axis being defined by a proximal end and a distal end of the needle;

applying a vacuum to remove the tissue sample from the needle through the biopsy apparatus; and

placing the needle in the first position for withdrawal from the patient.

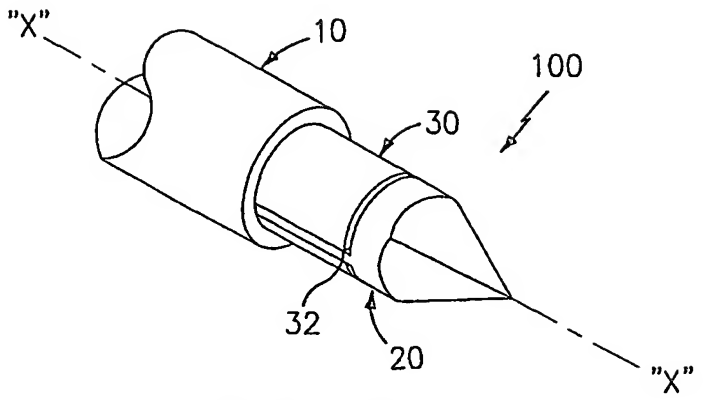


FIG. 1A

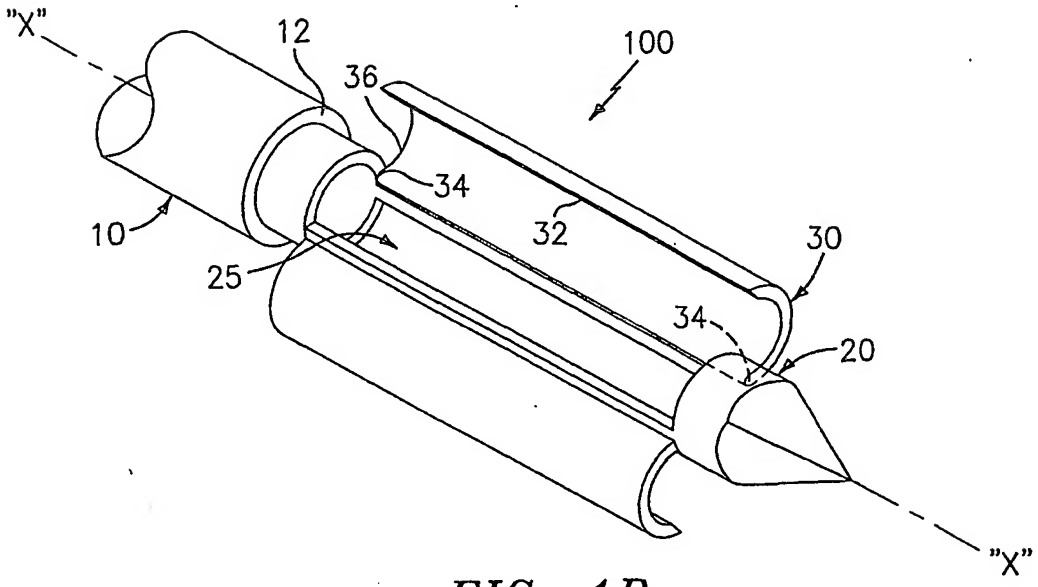
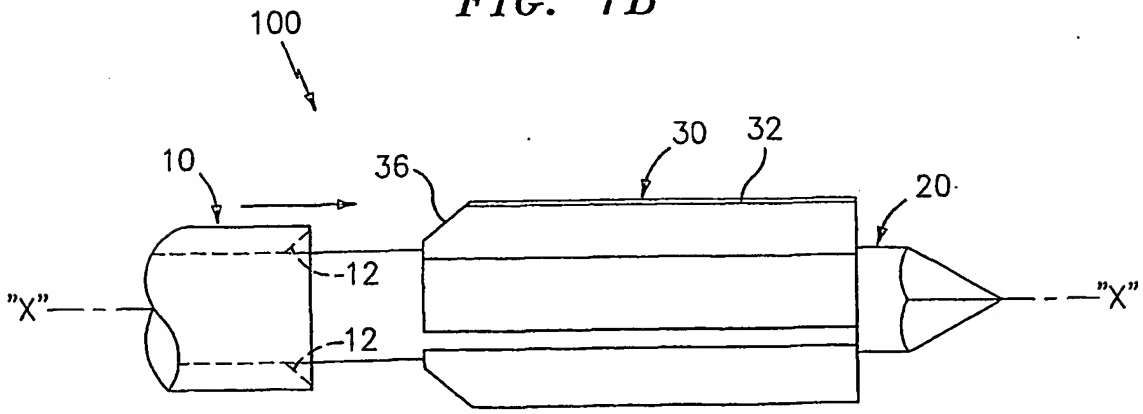


FIG. 1B



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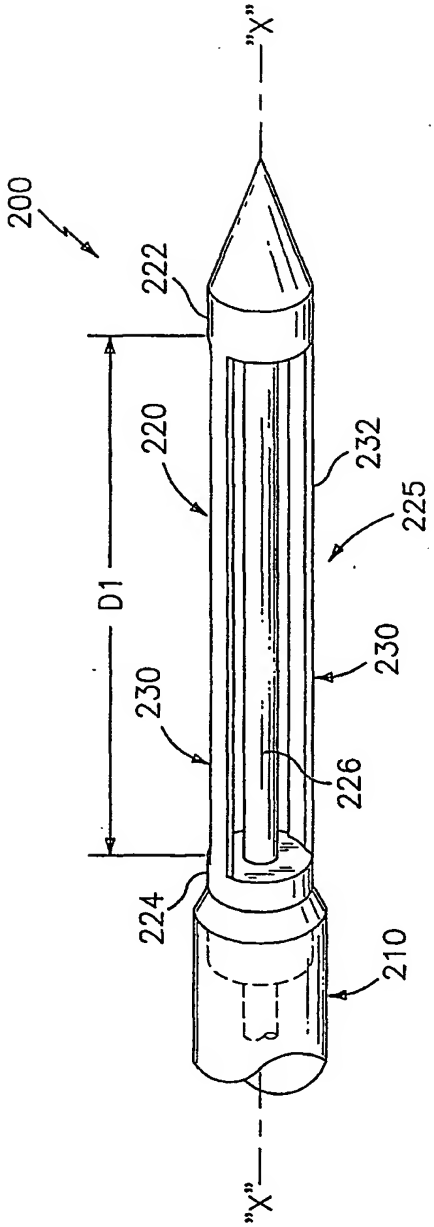
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220
232
225
D1
230
230
226
224
210
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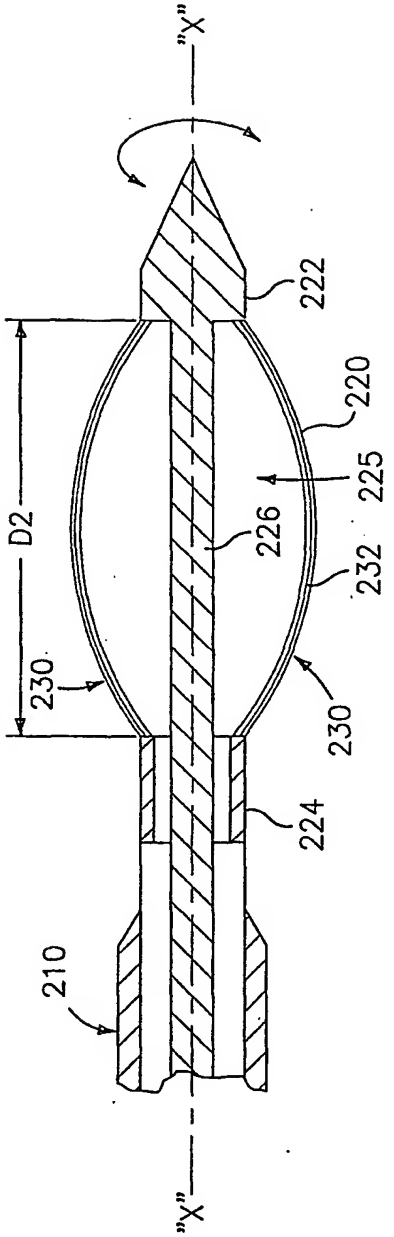
"X"

FIG. 2A


"X"
222
220
D2
225
226
232
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230
224
210
"X"

FIG. 2B

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/02931

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 794 626 A (KIETURAKIS MACIEJ J) 18 August 1998 (1998-08-18) column 3, line 58 -column 4, line 26; figures 2,3	1-3,6,7
X	US 1 867 624 A (JOSEPH HOFFMAN WILLIAM) 19 July 1932 (1932-07-19)	1,2
A	page 3, left-hand column, line 24 - line 30 page 3, right-hand column, line 68 - line 98; figures 17-19	3-5
A	WO 89 05608 A (COATS VIYELLA MEDICAL LTD) 29 June 1989 (1989-06-29) column 4, line 28 -column 5, line 2; figures 2,4	4

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 May 2002	06/06/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Mayer, E

Form PCT/ISA/210 (second sheet) (July 1998)

In ional Application No
PCT/US 02/02931

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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